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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/803,778	03/12/01	MAPLESON	B 1324.024A

023405 HM12/1012  
HESLIN ROTHENBERG FARLEY & MESITI PC  
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EXAMINER

FIELDS, I

ART UNIT

PAPER NUMBER

1645

DATE MAILED:

10/12/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/803,778		MAPLESON ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Iesha P Fields		1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) \_\_\_\_\_ is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

- |  |  |
|--|--|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                    | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 20) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

Applicant's Preliminary Amendment received April 23, 2001 has been received and entered. Claims 6 was cancelled, and claims 3-4, 7-9 (renumber 6-8), 12, 14, and 17-18 were amended. Consequently claims 1-19 are pending in the instant application.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States

**1. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Shanbrom *et al.***

The claims are drawn to a method of removing bacterial endotoxin from a pharmaceutical drug or vaccine substance by treating the solution with an ionic surfactant and then filtering the solution through a molecular weight cut-off filter.

Shanbrom *et al.* (EP O 083 999, 1983) disclose a method of removing bacterial endotoxin from an pharmaceutical drug or vaccine substance by treating the solution with an ionic surfactant and then filtering the solution through a molecular weight cut-off filter. Shanbrom *et al.* further disclose a method of removing bacterial endotoxin from an pharmaceutical drug or vaccine substance wherein the amphiphilic pharmaceutical drug

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or vaccine substance comprises a glycoprotein. Shanbrom *et al.* further disclose a method of removing bacterial endotoxin from an pharmaceutical drug or vaccine substance wherein the amphiphilic pharmaceutical drug or vaccine substance is a viral antigen.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**2. Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable in view of McIntire *et al.* and Schindler *et al.***

The claims are drawn to a method of removing bacterial endotoxin from a pharmaceutical drug or vaccine substance by treating the solution with the surfactant deoxycholate at various concentrations and then filtering the solution through a polysulfone membrane.

The teachings of Shanbrom *et al.* are set forth above. Additionally, Shanbrom *et al.* teach of a further process step in which the solution is subjected to dialysis.

Shanbrom *et al.* do not teach of a method of removing bacterial endotoxin from a pharmaceutical drug or vaccine substance by treating the solution with the surfactant deoxycholate at various concentrations and then filtering the solution through a polysulfone membrane.

McIntire *et al.* (Biochemistry 8: October 1969 p.4063-66) teach of a method of removing bacterial endotoxin from a pharmaceutical drug or vaccine substance by treating the solution with the surfactant deoxycholate (DOC) at various concentrations.

Schindler *et al.* (Journal of Immunological Methods, September 1989 p. 159-165) teach of a method of removing bacterial endotoxin using ultrafiltration with polysulfone.

Given that 1) Shanbrom *et al.* has taught of a method of removing bacterial endotoxin from an pharmaceutical drug or vaccine substance and then subjecting the solution to dialysis and that 2) McIntire *et al.* has taught of a method of removing

bacterial endotoxin from an pharmaceutical drug or vaccine substance by treating the solution with the ionic surfactant deoxycholate at various concentrations and that 3) Schindler *et al.* has taught of a method of removing bacterial endotoxin using ultrafiltration with polysulfone it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to remove bacterial endotoxin from an pharmaceutical drug or vaccine substance with the surfactant deoxycholate using ultrafiltration with polysulfone. One would have been motivated to use such a method in view of the teachings of Sweadner *et al.* (Applied and Environmental Microbiology, October 1977 p. 34:382-85) that employing such a method would reduce the problem of bacterial contamination in biological and pharmaceutical products.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iesha P Fields whose telephone number is (703) 605-1208. The examiner can normally be reached on 7am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 308-4242 for After Final communications.


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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ilesha P. Fields

October 1, 2001



MARK NAVARRO  
PRIMARY EXAMINER